



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Bradley C. Linden et al.

Serial No.: 09/121,368

Filed : July 23, 1998

For : INTRA-VASCULAR DRUG DELIVERY
CATHETER AND METHOD

Docket No.: S13.12-0036

Group Art Unit:

Examiner:

DECLARATION OF PETER T. KEITH

I, Peter T. Keith, a citizen of the United States of America, residing at (address), hereby declare that:

1. I am co-inventor of the subject matter claimed in U.S. Patent No. 5,538,504 to Linden et al., issued July 23, 1996 and entitled INTRA-EXTRAVASCULAR DRUG DELIVERY CATHETER AND METHOD for which I solicit a reissue pursuant to 35 U.S.C. § 251.

2. I have reviewed and fully understand the contents of the above-referenced patent, including the specification, original claims and the new claims. I believe the named inventors to be the first and original inventors of the subject matter which is claimed and for which a reissue is sought. I acknowledge my duty to disclose information which may be material to examination of the application.

3. I believe my original patent to be wholly or partly inoperative because I claimed less than I had a right to claim in the original patent. I believe the claims in my original patent do not reflect the full breadth of my invention for the reasons set forth below.

4. All errors corrected in this reissue application up to the date of filing this declaration arose without deceptive intent.

5. The claims in my original patent are directed to a method and apparatus for treating a vessel. However, the claims need not be limited to a vascular treatment site. The true method and apparatus of the present invention is directed to a generic treatment site accessed via a vascular path. As such, it was error to fail to clearly distinguish between the treatment site and the

delivery path, wherein the treatment site is generic and the delivery path is vascular. New independent claims 57, 74, 82, 91, 103, 110, 116, 120, 125, 130, 132, 140, 142, 143, 147, 151, 155 and all claims dependent therefrom overcome this error by reciting generic cardiac tissue as the treatment site (e.g., coronary vessel, myocardium, pericardium, endocardium, etc.).

6. The apparatus claims in my original patent are directed to a drug delivery device. However, the claims need not be limited to drug delivery as the therapeutic means. Studies have demonstrated that the act of puncturing or otherwise causing an injury at the treatment site may trigger a healing response that ultimately cures the injury and the underlying ailment. These studies suggest that causing an injury (e.g., by penetrating tissue) and drug delivery may act independently or in concert to render the desired therapy. As such, it was error to limit the apparatus claims to a therapeutic means comprising drug delivery alone. New independent claims 57, 74, 82, 91 and all claims dependent therefrom overcome this error by generically reciting a therapeutic catheter, independent of drug delivery.

7. The errors identified above, namely the unnecessary limitations to a vascular treatment site and drug delivery, are exasperated by recent judicial clarification of the role of preambles in claim interpretation. For example, in Rowe v. Dror et al., 42 U.S.P.Q.2D 1550 (CAFC, 1997), the court interpreted the recitation of, "angioplasty" (a medical procedure) in the preamble to impart a structural limitation. Therefore, it was error to include the vascular treatment site and drug delivery recitations in the preamble of the claims in my original patent because such recitations may be interpreted to limit the scope of the invention. Claims 57, 74, 82, 91, 103, 110, 116, 120, 125, 130, 132, 140, 142, 143, 147, 151, 155 and all claims dependent therefrom modify the preamble to avoid such an interpretation and overcome this error.

8. I acknowledge that willful false statements and the like are punishable by fine or imprisonment, or both under 35 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon. All statements made herein based on my own knowledge are true and all statements made herein based on information and belief are believed to be true.

Date:

9/29/98

Peter T. Keith





#3

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Group Art Unit:

Examiner:

DECLARATION OF ROBERT E. ATKINSON

I, Robert E. Atkinson, a citizen of the United States of America, residing at (address), hereby declare that:

1. I am co-inventor of the subject matter claimed in U.S. Patent No. 5,538,504 to Linden et al., issued July 23, 1996 and entitled INTRA-EXTRAVASCULAR DRUG DELIVERY CATHETER AND METHOD for which I solicit a reissue pursuant to 35 U.S.C. § 251.

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Date:

Nov 6, 1998

R. Atkinson

Robert E. Atkinson



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Docket No.: S13.12-0036

Group Art Unit:

Examiner:

DECLARATION OF DR. BRADLEY LINDEN, M.D.

I, Dr. Bradley Linden, M.D., a citizen of the United States of America, residing at (address), hereby declare that:

1. I am co-inventor of the subject matter claimed in U.S. Patent No. 5,538,504 to Linden et al., issued July 23, 1996 and entitled INTRA-EXTRAVASCULAR DRUG DELIVERY CATHETER AND METHOD for which I solicit a reissue pursuant to 35 U.S.C. § 251.

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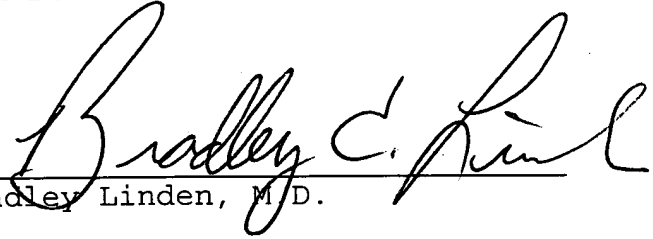
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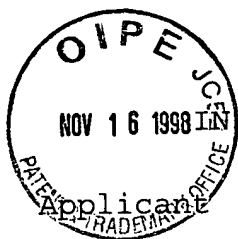
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Date:

11/3/98

Dr. Bradley Linden, M.D.

A handwritten signature in cursive script, reading "Bradley C. Linden", written over a horizontal line.



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Examiner:

DECLARATION OF DR. DONALD F. PALME, II

I, Dr. Donald F. Palme, II, a citizen of the United States of America, residing at (address), hereby declare that:

1. I am co-inventor of the subject matter claimed in U.S. Patent No. 5,538,504 to Linden et al., issued July 23, 1996 and entitled INTRA-EXTRAVASCULAR DRUG DELIVERY CATHETER AND METHOD for which I solicit a reissue pursuant to 35 U.S.C. § 251.

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Date:

10/9/98

Donald F. Palme II

Dr. Donald F. Palme, II